REMARKS

Status of the Claims

Claims 7-9 are pending in this application. Claim 7 has been amended as described elsewhere herein. Support for this amendment is set forth in the Remarks, below, or can found in the original claims as filed. Thus, no new matter has been added by way of amendment.

Withdrawal of Rejections Under 35 U.S.C. § 112, 1st ¶, Written Description

Applicants note with thanks the withdrawal of the written description rejections in the Advisory Action mailed 10 Sep 2007.

The Claims Rejections Under 35 U.S.C. § 112, 1st ¶, Enablement, Should Be Withdrawn

Claims 7-9 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly nonenabled. Applicants respectfully traverse.

The Office has repeatedly alleged that the claimed subject matter could not be used for cancer therapy to reduce cancer cell growth. The rejection should be withdrawn for two (2) main reasons.

Reason (1) The rejection construes the claims as if they recite an endpoint of tumor reduction. Applicants have brought this erroneous construction to the attention of the Office without avail. None of the claims group currently under examination by the Office recited "treating cancer," "cancer treatment," "tumor reduction," or the like, nor do any of the currently pending claims recite "treating cancer," "cancer treatment," "tumor reduction," or the like. Contrary to MPEP § 2107.02, the Office Action is reading into the claim limitations that are not there. Thus, the rejection should be withdrawn because it is based the legally unsupportable construction that the claims require a step of successfully treating cancer or reducing tumor size.

Applicants take issue with several specific statements made in the Advisory Action, as well. For instance, the Action erroneously states that "[t]he claims do not recite the use of adjuvants with SEQ ID NO:25…." See the Advisory Action, page 5,

third full paragraph. Applicants' representative respectfully draws attention to claim 9, which expressly recites adjuvants. This error is compounded in the next section of the Advisory Action, which states that the claims "are not drawn to a method for inducing an immune response, using SEQ ID NO:25 and an adjuvant...." Once again, Applicants' representative requests that claim 9 be reviewed because it expressly recites adjuvants.

Immediately upon the heels of these mistakes, the Advisory Action returns to its core misconstruction of the claims by arguing that "...one cannot predict which CTL peptides, including the claimed SEQ ID NO:25, would be effective in treating cancer." The rejection and the incorrect construction on which the rejection is founded must be withdrawn.

Reason (2) The improper claim construction allows the enablement analysis to overlook *bona fide* uses for Applicants' claimed method for inducing an immunoresponse. Applicants have disclosed that their methods can be used "to generate antibodies or reagents specific for the polypeptide of the present invention, as diagnostic reagents to detect...genetic or biochemical markers in blood or tissues that will enable the detection of very early changes along the carcinogenesis pathway will help in determining the best treatment for the patient." See paragraphs [0182]-[183]. Those of skill in the art understand that such "surrogate tumor markers" can be used to diagnose and stage different forms and states of cancer. See paragraph [0183]. For example, one could easily use these markers to compare the expression of a particular gene between a diseased tissue and a normal tissue. See paragraph [0184]. The comparison can be made at the protein level. See paragraph [0188]. Those of skill in the art can also easily detect tumor marker expression levels and subcellular localization by using antibodies to the corresponding protein. See paragraph [0200]. Antibodies for use in the method are easy to make and can be obtained by administering the polypeptides or epitope-bearing fragments to an animal, which may be a non-human animal, using routine protocols.

However, these uses have received no examination due to the Office Action's improper claim construction. Indeed, the Advisory Action continues to allege that

demonstrating that a peptide fragment produces an immunological response, as Applicants have done throughout the Examples, "...does not necessarily lead to any result of any practical use." See page 9 of the Advisory Action. Applicants continue to request that the utilities set forth in the specification, including those recited in the paragraph above, be examined. The present rejection should be withdrawn so that complete examination can take place (complete examination is required under the Compact Prosecution Rule, MPEP § 2106(II).

Miscellaneous. There are additional deficiencies in the rejection, as well. These are described in the following two paragraphs.

First, the Office has repeatedly relied upon the reference to White *et al*. for the premise that Applicants' claimed method would not work because of "...internalization or down-regulation of the antigen or the MHC molecules...." Applicants representative has pointed out that White does not provide any evidence that the relevant antigen of the present claims, i.e., HASH2 (SEQ ID NO:2) is either internalized or down-regulated. Consequently, the Examiner was invited to provide some reference to support such a premise or to provide an affidavit pursuant to 37 CFR 1.104(d)(2) if the premise is based upon personal knowledge. None has been forth coming and this point of the rejection therefore cannot be relied upon by the Office.

The Advisory Action also asserts that "...there is no indication that amino acid sequences comprising SEQ ID NO:25 and are longer than 12 amino acids would induce [a] CTL response...." See the Advisory Action, page 10. Applicants request that this statement be compared against Example 10 of the specification, because the Example favors a conclusion that such peptides would induce a response in CD4+ cells. Despite this evidence, the Advisory Action alleges that it is unpredictable whether other such peptides besides those described in Example 10 would induce a CD4+ T cell response. Applicants representative duly points out that the only evidence of record favors a conclusion that such peptides do induce a CD4+ response. It is now the Examiner's burden to come forth with some evidence or legally supportable findings to counter Applicants evidence, or cease reliance upon the conclusory statement that "...there is

no indication that amino acid sequences comprising SEQ ID NO:25 and are longer than 12 amino acids would induce [a] CTL response…."

CONCLUSION

In view of the remarks herein above, Applicants respectfully submit that the rejection of claims 7-9 is overcome. Accordingly, Applicants submit that this application is now in condition for allowance. Early notice to this effect is solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment particularly including any fees required under 37 CFR §1.16 or 1.17, and any necessary extension of time fees, to Deposit Account No. 07-1392.

Respectfully submitted,

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